

**Notice of Allowability**

Application No.

09/872,868

Applicant(s)

GARDNER ET AL.

Examiner

Art Unit

Gerald G Leffers Jr., PhD

1636

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed 5/7/2004.
2. ☒ The allowed claim(s) is/are 1-16.
3. ☒ The drawings filed on 24 September 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>3/3/03</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                             | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

### **EXAMINER'S AMENDMENT**

Receipt is acknowledged of a response filed by applicants on 5/7/2004. In the amendment filed 5/7/2004 several claims were cancelled (claims 17-30) and claims were amended (claims 1 & 12-13). Claims 1-16 are allowed. The following examiner's amendment to the specification is made to update the status of a related application, 09/872,338, which is cited on the first page of the specification (see the amendment to the specification filed 8/11/2003).

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the specification:

At page 1, line 13, the phrase --and now U.S. Patent No. 6,737,269,-- has been inserted after the words "filed June 1, 2001" and prior to the words "the disclosures of which".

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: applicants' arguments and amendment of the claims have obviated all of the outstanding grounds of rejection. In particular, in order to maintain the art rejections of record over the teachings of Bailey et al (U.S. Patent No. 5,416,008), the examiner would have to be able to demonstrate that the particular

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construct VIII exemplified in Example 2 would necessarily act as a bistable genetic toggle switch as recited in the claims and defined in the instant specification. For example, there is no convincing evidence in the teachings of Bailey et al that their exemplified embodiment would necessarily remain in the “high” expression state for CAT even in the absence of the IPTG inducer. Applicants have demonstrated that it is the relative promoter/operator/repressor strengths that function to allow the genetic switch to function as a genetic “toggle” where the system is stably maintained in one state or the other in the absence of a switching agent. While applicants have not produced data that indicates that the exemplified embodiment taught in Example 2 would necessarily not possess the characteristics that are recited in the amended claims, the examiner cannot point to convincing evidence that the specific embodiment taught by Bailey et al would *necessarily* possess the characteristics of a genetic toggle switch as recited in the amended claims. Therefore, the examiner would not be able to sustain an inherency argument for rejecting the instant claims over the teachings of the Bailey et al patent. Nor do Bailey et al teach or suggest applicants’ approach for optimizing the combination of promoter/operator/repressor elements for developing a genetic “toggle switch” as is recited in the instant claims and described in the instant specification. Thus, the amended claims are free of the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

***Information Disclosure Statement***

A supplemental copy of the PTO Form 1449 for the information disclosure statement filed 3/03/2003 has been mailed with this action. On the copy mailed with the office action of 4/9/2003 the examiner inadvertently did not initial the cited patent and application documents. This has been corrected on the supplemental copy of the PTO Form 1449. All references cited on the IDS have been fully considered.


***Conclusion***

Claims 1-16 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636  
  
GERRY LEFFERS  
PRIMARY EXAMINER

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